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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,431	12/06/2001	Shinji Kondo	216109US2X	8204
22850	7590	06/01/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			NASSER, ROBERT L	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,431

Applicant(s)

KONDO ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, 18-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's election with traverse of Species I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that no reasons for given to support the restriction requirement. This is not found persuasive because the examiner did not make a restriction requirement, but rather an election of species. As such, the evidence in support of the requirement is different and the examiner met his burden. It has been determined by the examiner, however, that the species are not patentably distinct, as will be demonstrated below. Accordingly, the requirement is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 4-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the specification, applicant recites in columns 7-8 that the maximum pressure is the pressure during inflation of the cuff, when the signal from the optical sensor stops fluctuating (see column 7, line 15). It then states that cuff is inflated to a predetermine pressure, and deflated. The point where the optical signal begins fluctuating again is determined to be the minimum pressure. The examiner previously objected saying that these two pressures were the same. Applicant responded saying that due to blood pooling after the vessel is sealed during measuring of maximum pressure, the minimum pressure would be different. Assuming this to be true, it would

seem that the minimum pressure would be greater than the maximum pressure, as the blood pooling would cause the vessel to open at a higher pressure than when the vessel closed.

In the art, maximum pressure refers to systolic pressure, or the pressure where the vessel closes off during inflation of a cuff, and minimum pressure refers to diastolic pressure, or the pressure where blood flow returns to normal after the cuff is opened during deflation. This contradicts applicant's uses of the terms and it is unclear exactly what applicant is measuring.

Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 is rejected in that it directly contradicts claim 18, from which it depends. Claim 18 positively recites that the pulse wave is determined. Claim 35 states that if it is not determined. . . Since claim 18 states that the pulse wave is determined, there can be no situation for the pulse wave not to be determined, as recited in claim 35.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 18, 20, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Masuda et al. Masuda et al shows a blood pressure measuring system including a photoelectric sensor for measuring the pulse wave having a light emitting and receiving portions 44a, 44b, and 46, a blood pressure meter, and a control portion 29 that receives the output of the photoelectric sensor and determines the volumetric pulse wave, which is a signal that changes with the change in volume of the blood vessels. The blood pressure meter determines both systolic and diastolic pressure based on the photoelectric sensor output, for each stroke of the heart when the device is in monitor mode. The system of Masuda et al also calculates the heart rate.

Claims 1, 3, 5, 6, 18, and 20-23, rejected under 35 U.S.C. 102(b) as being anticipated by Oka et al 5,743,856. Oka shows in the first embodiment, figures 1-5, a system that measures blood pressure with a cuff based on the oscillometric method of measuring pressure, and a control means that associates a pulse wave minimum with minimum pressure and a pulse wave maximum with maximum pressure. In column

16, lines 43-65, Oka et al states that the PPW sensor 46 may be an photoelectric measuring device. Therefore, Oka et al anticipates the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Tochikubo et al. Oka et al detects the volume pulse wave. Tochikubo et al further detects pulse wave based on arterial displacement. Hence, it would have been obvious to modify Oka et al to measure the pulse wave through arterial displacement, as it is merely the substitution of one known measurement method for another.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al et al in view of Bryars et al. Oka et al does not teach the structure of the pulse wave sensor in as much as it does not show how it attaches to the body. Bryars et al further shows the recited structure of an optical pulse sensor. Hence, it would have been obvious to modify Oka et al to use the structure of Bryars, as it is merely the substitution of one known equivalent sensor for another.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Bryars, as applied to claim 7 above, further in view of Ota et al. Ota et al further teaches that the blood pressure measurement like that of the above combination

must be compensated for the angle of inclination of the arm relative to the heart.

Hence, it would have been obvious to modify the above combination to perform such a compensation, so as to increase the accuracy of the readings.

Claims 9, 10, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Mathews. Oka et al does not compensate for body motion. Mathews uses a second optical sensor to measure noise due to body movement and subtract the signal from the measurement signal to provide a signal free from the effects of noise. Hence, it would have been obvious to modify Oka et al to provide such a noise correction, to improve the accuracy of the readings. With respect to claims 10 and 26, the examiner takes official notice that it would have been obvious to provide a filter for the noise signal, to eliminate artifacts at a frequency obviously not due to body motion.

Claims 11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Masuda et al. Oka et al does not determine the pulse rate in the embodiment of figure 1. Masuda et al teaches that it is known in a blood pressure meter to also measure pulse rate, to provide more information to the physician. Hence, it would have been obvious to modify Oka et al to also determine pulse rate, to provide the physician with a more complete picture of a patient's condition.

Claims 12 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Heinemann et al. Oka et al does not teach adjusting the intensity of the light source. However, Heinemann et al teaches that such an adjustment is desirable to keep the detector output intensity constant over the

measurement range. Hence, it would have been obvious to modify Oka et al to use such an intensity adjustment, to provide continuity of measurement from one to the next.

Claims 13 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Clark et al. Clark et al further teaches that it is known in optical systems to provide automatic gain control to keep the measurement signals within the operating range of the system. Hence, it would have been obvious to modify the above combination to provide such gain control, to avoid errors in measurement.

Claims 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al et al in view of Yokozeki. Yokozeki et al shows a combined blood pressure meter blood-amount measuring device. Hence, it would have been obvious to modify Oka et al to include a blood amount measuring device, to provide the clinician with a more complete picture of the patient's condition.

Claims 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al in view of Oka et al. Nomura et al shows a system to measure depth of anesthesia from the pulse wave. It would have been obvious to modify Nomura to use the optical pulse wave measuring device of Oka et al, as it is merely the substitution of on known equivalent pulse wave sensing device for another.

Claims 16, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Hosaka et al. Masuda measures propagation time between an ecg device and a photoelectric sensor. Hosaka teaches that a second optical detector may be substituted for the ecg device in measuring propagation time.

Hence, there would be two photoelectric sensors. Hence, it would have been obvious to modify Oka et al to use a second optical sensor, as it is merely the substitution of one known sensor for another. Hosaka further teaches that propagation time is an indicator of coronary artery disease (arteriosclerosis). Hence, it would have been obvious to modify Masuda et al to provide such an artery disease indication, to provide the clinician with a more complete picture of the patient's condition.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Tochikubo et al. Masuda et al detects the volume pulse wave. Tochikubo et al further detects pulse wave based on arterial displacement. Hence, it would have been obvious to modify Masuda et al to measure the pulse wave through arterial displacement, as it is merely the substitution of one known measurement method for another.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Ota et al. Ota et al further teaches that the blood pressure measurement like that of Masuda must be compensated for the angle of inclination of the arm relative to the heart. Hence, it would have been obvious to modify Masuda to perform such a compensation, so as to increase the accuracy of the readings.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Ota et al. Ota et al further teaches that the blood pressure measurement like that of Oka et al must be compensated for the angle of inclination of the arm relative to the heart. Hence, it would have been obvious to modify Oka et al to perform such a compensation, so as to increase the accuracy of the readings.

Claims 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Mathews. Masuda does not compensate for body motion. Mathews uses a second optical sensor to measure noise due to body movement and subtract the signal from the measurement signal to provide a signal free from the effects of noise. Hence, it would have been obvious to modify Masuda et al to provide such a noise correction, to improve the accuracy of the readings. With respect to claims 10 and 26, the examiner takes official notice that it would have been obvious to provide a filter for the noise signal, to eliminate artifacts at a frequency obviously not due to body motion.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Heinemann et al. Masuda et al does not teach adjusting the intensity of the light source. However, Heinemann et al teaches that such an adjustment is desirable to keep the detector output intensity constant over the measurement range. Hence, it would have been obvious to modify Masuda et al to use such an intensity adjustment, to provide continuity of measurement from one to the next.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Clark et al. Clark et al further teaches that it is known in optical systems to provide automatic gain control to keep the measurement signals within the operating range of the system. Hence, it would have been obvious to modify the above combination to provide such gain control, to avoid errors in measurement.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Yokozeki. Yokozeki et al shows a combined blood pressure meter

blood-amount measuring device. Hence, it would have been obvious to modify Masuda et al to include a blood amount measuring device, to provide the clinician with a more complete picture of the patient's condition.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al in view of Masuda et al. Nomura et al shows a system to measure depth of anesthesia from the pulse wave. It would have been obvious to modify Nomura to use the optical pulse wave measuring device of Masuda et al, as it is merely the substitution of on known equivalent pulse wave sensing device for another.

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Hosaka et al. Masuda measures propagation time between an ecg device and a photoelectric sensor. Hosaka teaches that a second optical detector may be substituted for the ecg device in measuring propagation time. Hence, there would be two photoelectric sensors. Hence, it would have been obvious to modify Masuda to use a second optical sensor, as it is merely the substitution of one known sensor for another. Hosaka further teaches that propagation time is an indicator or coronary artery disease (arteriosclerosis). Hence, it would have been obvious to modify Masuda et al to provide such an artery disease indication, to provide the clinician with a more complete picture of the patient's condition.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Hersh et al. In column 4, lines 31-41, Hersh et al teaches that in general in the medical field, if a signal is unobtainable due to artifact, an average of previous

signals may be used in its place. It would have been obvious to modify Masuda to use this technique, to increase the accuracy of readings.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al in view of Hersh et al. In column 4, lines 31-41, Hersh et al teaches that in general in the medical field, if a signal is unobtainable due to artifact, an average of previous signals may be used in its place. It would have been obvious to modify Oka et al to use this technique, to increase the accuracy of readings.

Claims 18 and 36 are allowable. Claims 18 and 36 define over the art in that none of the heart determines the pulse wave by optically monitoring movement of the heart itself, as opposed to blood vessels.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 34 defines over the art of record in that none of the art also determines all three parameters, as claimed.

Applicant's arguments filed 3/8/2004 have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1-17 have been found convincing. However, the arguments have been deemed to be moot in view of the new grounds of rejection.

Applicant did not amend claims 18-35 as stated in the response. In fact, applicant has made no amendment to claims 18-35 and applicant has not argued these

claims. Accordingly, the rejection based on Masuda is being maintained on these claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
May 28, 2004



ROBERT L. NASSER
PRIMARY EXAMINER